TEXAS DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL
Application for Mammography Accreditation and Certification

Complete all items of the application in accordance with Title 25 Texas Administrative Code (TAC) §289.230. Please print or type. *Failure to furnish the requested information/documentation may result in a delay of the application review and/or disapproval of your application.* Retain a copy of the application for your files. **Submit the appropriate fee(s), the completed application and a copy of the application and all documentation to *either* address**:

Postal service address:
Texas Department of Health
Bureau of Radiation Control
Texas Mammography Accreditation Program
P.O. Box 149200
Austin, Texas 78756-3189

Overnight/express service or personal delivery address:
Texas Department of Health
Bureau of Radiation Control-N127
Texas Mammography Accreditation Program
8407 Wall Street
Austin, Texas 78754

If there are any questions, contact the Bureau of Radiation Control at (512) 834-6688.

Section 1: General Information

Employer Identification Number (EIN): _____

Legal Name of Facility: _____

DBA(if applicable): _____

Mailing Address:(Street/City/State/Zip)

_____

_____

_____

Machine Use Location Address:(Street/City/State/Zip)
(If multiple use locations, use additional sheets)

_____

_____

_____

Mammography Facility Phone Number: _____ FAX #: _____

Radiation Safety Officer: _____
Telephone #: _____ E-mail address: _____

Lead Interpreting Physician: _____
Telephone #: _____ E-mail address: _____

Contact Person & Title: _____
Telephone #: _____ E-mail address: _____

Section 2: Facility Practice and Procedure Information

1. Type of Facility: *check one*
   - ” Hospital
   - ” Surgical Office
   - ” Hospital Outpatient Center
   - ” Mobile (multiple locations)
   - ” Clinic (specify type) _____

2. Total number of machines:
   - Mammography units: _____
   - Breast biopsy units: _____

3. Which of the following mammographic procedures does your facility perform? *Check all that apply*
   - ” Screening
   - ” Diagnostic
   - ” Self-Referral

4. Average number of procedures performed per year at the facility:
   - _____ Screening
   - _____ Diagnostic
   - _____ Aggregate (Total)

Section 3: Self-referral Authorization

Do you wish to perform self-referral mammography? ” Yes ” No

If you answered yes, complete this section.

To perform self-referral mammography, you must have authorization. {25 TAC §289.230(h)} Please submit the following information and documentation for self-referred mammography patients:

- ○ How many views are taken for a typical mammogram? _____
- ○ What views are taken for a typical mammogram? _____
- ○ **State** the age range of the population to be examined and the frequency of the exam following established, nationally recognized criteria of the American Cancer Society, American College of Radiology, the National Council on Radiation Protection and Measurements, or other criteria recognized by the Mammography Accreditation Program.
- ○ **Attach** written dated procedures for advising individuals and their private physicians of the results of the self-referred exam and any further medical needs indicated. Include a method of follow-up to confirm that patients with positive findings, as well as practitioners, have received proper notification.
- ○ **Attach** a description of the methods used to educate patients in self-examination techniques, and on the necessity for follow-up by a physician. List the names of the brochures and if used, the title of the video.
- ○ **Attach** film retention policy.

Section 4: Mammography Equipment

*Complete this section for each mammographic x-ray unit. Breast biopsy units must be certified in Texas, accreditation is not required at this time. Check **all** appropriate boxes. Include a copy of a current medical physicist report for each machine. (Note - if there are any failures and/or deficiencies on the report, attach a list of corrective actions. Include copies of service/work invoices with the description of corrective actions.)*

" Located Onsite ***or*** " Mobile unit

Indicate which services this machine is used for, check all that apply:

" Mammography " Breast Biopsy

1. Control Panel Manufacturer: _____ Control Panel Model Name & Number: _____ Control Panel Serial Number: _____

2. This machine is used for: " Screening " Diagnostic " Magnification

3. Target(s) & Filter(s) available: " Mo/Mo " Mo/Rh " Rh/Rh " W/Al " W/Mo " W/Rh

4. Exposure Control: " Phototimed " Manual

5. Type of imaging system: " Screen/Film " Digital
   Screen/Film Combination: Screen:_____ Film:_____

6. Analysis of Phantom Image: Phantom manufacturer and model number:_____

   Technique used for phantom: kVp_____ mAs_____ *or* mA_____ & time_____
   Mode used: " AEC " AOP " Auto kVp " Other_____

Check all objects that are visualized on the phantom:

Fibers:
" 1.56 millimeters
" 1.12 millimeters
" 0.89 millimeters
" 0.75 millimeters
" 0.54 millimeters
" 0.40 millimeters
Must see entire fiber to count as a whole.

Specks:
" 0.54 millimeters
" 0.40 millimeters
" 0.32 millimeters
" 0.24 millimeters
" 0.16 millimeters
How many specks in last group? _____

Masses:
" 2.00 millimeters
" 1.00 millimeters
" 0.75 millimeters
" 0.50 millimeters
" 0.25 millimeters
Must see rounded shape to count as a whole.

Section 5: Processing Equipment

Manufacturer:	Dedicated Mammography:	Model Number:	Serial Number:	Location:
_____	” Yes ” No	_____	_____	_____
_____	” Yes ” No	_____	_____	_____
_____	” Yes ” No	_____	_____	_____

If you have more than one processor, please indicate which is the main processor or the back-up processor(s).

Is batch processing utilized? ” Yes ” No

If yes, submit film transport procedures {25 TAC §289.230(j)}

Section 6: Mobile Services

If you checked mobile for any mammography equipment in Section 4, you will need to complete this section. {25 TAC§289.230(l)(8)}

- Main location where machine, records, etc. will maintained for inspection. This must be a street address, not a P.O. Box.

_____

Street City State Zip

- **Attach** a sketch or description of the normal configuration of the mammography unit’s use including the operator’s position and any ancillary personnel’s location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator’s location.

Section 7: Legal name of business, facility or individual

A Franchise Tax Information Form (BRC Form 226-1) must be submitted for all new applications and for any name change or ownership change.

Section 8: Personnel Qualifications

List all personnel involved with the mammography facility. For each individual, fill out the appropriate checklist and attach the required documentation to the form. Make copies of the forms as needed.

Interpreting Physician(s):

Name:

Radiologic Technologist(s) performing mammography:

Name:

Medical Physicist(s):

Name:

Section 9: Certification

I certify that all information submitted with this application is true and current to the best of my knowledge.

*Typed or printed name and title	Date	Signature
Typed or printed name of person who completed application	Date	Signature

**This shall be the signature of the Administrator, President, Chief Executive Officer, Owner or Partner of the facility.*

As the **lead interpreting physician**, I do hereby affirm that I assume the responsibilities in 25TAC§289.230 (k)(1)(A) in association with this application.

Typed or printed name of lead interpreting physician	Date	Signature

Section 10: Radiation Safety Officer

Name:_____

- **Attach** qualifications as required in 25 TAC §289.226(s)(1).

As **radiation safety officer** for this facility, I do hereby assume those duties and responsibilities as listed in 25 TAC 289.226(s)(2). I certify that all information submitted with this amendment is true and current to the best of my knowledge.

Typed or printed name of radiation safety officer	Date	Signature

This MQSA Information Release Authorization must be signed by the Administrator, President, CEO, Owner, or Partner and the lead interpreting physician of the facility. Original signatures are required on this form. Stamps, electronic signatures or photocopied signatures are unacceptable.

MQSA Information Release Authorization

Effective October 1, 1994, all mammography facilities must be certified by the Food and Drug Administration (FDA), in accordance with the requirements of the Mammography Quality Standards Act (MQSA). The Texas Department of Health (TDH) has been designated by the FDA as one of the accreditation bodies in Texas for MQSA because its current accreditation program meets the standards contained in the MQSA law.

In order that facilities participating in the Texas Mammography Accreditation Program can obtain the required certification, the FDA will request the TDH to provide specific data about these facilities, units and personnel. The information would be drawn from the Application for Mammography Accreditation and other supporting documentation provided to TDH by the facility during the accreditation or re-accreditation process. Please complete the following authorization for release of information so that the necessary information may be forwarded to the FDA.

Authorization for Release of Information

"As the responsible parties of the mammography facility listed below, and in recognition of the need for this facility to be certified by the FDA, we hereby authorize the TDH to submit to the FDA any or all data about this facility that was submitted as part of its mammography accreditation or reaccreditation application, the survey report and findings made by the TDH, any other information about the facility that was submitted to the TDH or that the TDH currently has in its possession, and any other information gathered by the TDH in pre- or post-accreditation site visits by the TDH survey team."

Facility name and address: _____

_____

_____

_____ _____

Signature of Administrator, President, CEO, Owner, or Partner

Signature of lead interpreting physician

_____ _____

Typed or printed name

Typed or printed name

Executed on _____

Date

Checklist for Interpreting Physicians

Name: _____

You will need to make a copy of this form and use it for each interpreting physician at the facility. Please submit the requested document for each qualification listed below. ***Attach*** *the required documentation to each form.* ***Do not send copies of DEA numbers, Controlled Substance license, or a current ACR Section K.***

3. Initial qualifications:

- ” Texas Board of Medical Examiner’s License - (copy of current license)

Date you started interpreting mammograms or qualifying date as established by MQSA inspector: _____
(Month, Day , Year)

2. Based on the date stated above, select the proper category and submit the requested documentation.

If you qualified prior to 04-28-1999, you must submit documentation of the following:

- ” ABR, AOBR or other certification body approved by FDA - (copy of certificate), ***or***
  Equivalent formal training, which includes two months of documented full-time training in interpretation of mammograms, including instruction in radiation physics, radiation effects and radiation protection. (Letter from the residency program director)

- ” *40 hrs formal training in mammography (self-attestation ***or*** letter from residency program director)

- ” *have read and interpreted 240 mammograms under the direct supervision of a qualified interpreting physician within a 6 month period. (self-attestation ***or*** letter from residency program director)
  If you qualified prior to 10-01-1994, direct supervision was not applicable.

*Note: for those physicians who were in practice prior to October 1, 1994, a self-attestation will be accepted for those items with a * beside them. Self-attestations must state that these qualifications were met* ***“prior to 10-01-1994".*** *For physicians who completed their training after October 1, 1994, documentation must be submitted for all qualifications.*

If you qualified after 04-28-1999, you must submit documentation of the following:

- ” ABR, AOBR or other certification body approved by FDA - (copy of certificate), ***or***
  Equivalent formal training, which includes three months of documented full-time training in interpretation of mammograms, including instruction in radiation physics, radiation effects and radiation protection. (letter from the residency program director)

- ” 60 hrs formal training in mammography (letter from residency program director)

- ” If you **passed your board at the first available opportunity**, you will need to submit documentation that you have read and interpreted 240 mammograms under the direct supervision of a qualified interpreting physician within a 6 month period during the last 2 years of the residency program. (letter from residency program director) ***or***
  If you **did not take your board at the first available opportunity**, you will need to submit documentation that you read and interpreted 240 mammograms under direct supervision of a qualified interpreting physician within the six month period prior to qualifying as an interpreting physician. (letter from supervising physician)

3. Continuing experience and education:

- ” have read and interpreted mammograms for an average of 40 mammograms/month for 24 months (960 total) (Documentation of numbers from the facility are required, self-attestations are **not** allowed)

” 15 continuing education units (CEUs) in **mammography** over a 3 year period (copies of mammography certificates, *do not send any other certificates*)

Checklist for Radiologic Technologist

Name: _____

You will need to make a copy of this form and use it for each technologist at the facility who will be performing mammography. Please submit the requested document for each qualification listed below. Fill out the form completely and ***attach*** *the requested documentation to each form.*

1. Initial Qualifications:

- ” Medical Radiologic Technologist license - (copy of current license)

Date you started performing mammography or qualifying date as established by MQSA inspector: _____ (Month, Day, Year)

3. Based on the date stated above, select the proper category and submit the requested documentation.

If you qualified prior to 10-01-1994, you must submit documentation of the following:

- ” 20 hours of formal mammography training; (letter from training program; CME certificate; documentation from in-house training program or self-attestation)

Or

- ” ARRT(M) - (copy of card) Date examination was taken: _____

If you qualified from 10-01-1994 to 10-01-1996, you must submit documentation of the following:

- ” 20 hours of formal mammography training; (letter from training program; CME certificate; or documentation from in-house training program)

Or

- ” ARRT(M) - (copy of card) Date examination was taken: _____

If you qualified from 10-01-1996 to 08-10-1998, you must submit documentation of the following:

- ○ 40 hours of formal mammography training; (letter from training program; CME certificate; documentation from in-house training program)

  Note: During this time frame the FDA required 40 hours of formal training, but under certain circumstances accepted less. If you qualified with fewer hours, you must include a written statement that attests fewer hours were accepted by the MQSA inspector . Copies of the qualifying documentation must be submitted with the statement.

Or

- ” ARRT(M) - (copy of card) Date examination was taken: _____

If you qualified from 08-10-1998 to 04-28-1999, you must submit documentation of the followin:

- ” 40 hours of formal mammography training; (letter from training program; CME certificate; documentation from in-house training program)

If you qualified after 04-28-1999 you must submit documentation of the following:

- ” 40 hours formal training in mammography; (letter from training program; CME certificate; documentation from in-house training program)

- ” performed 25 mammograms under direct supervision
  (letter from training program; documentation from in-house training program)

4. Continuing experience and education:

- ” 15 CEUs in **mammography** over a 36 month period (copies of certificates)

As of April 28, 1999 you must document the performance of 200 mammograms over 24 months. Documentation of numbers from facilities will be required; **self-attestations are not accepted**. *(Inspectors will start reviewing records 04-28-2001.*

Checklist for Medical Physicist

Name: _____

You will need to make a copy of this form and use it for each medical physicist at the facility who will be performing the annual mammography system survey. Please submit the requested document for each qualification listed below. Fill out the form completely and ***attach*** *the requested documentation to each form.*

1. ” Texas Medical Physics Practice Act license - (copy of current license)

Qualifying date as established by MQSA inspector: _____
(Month, Day, Year)

2. Select the proper category and submit the requested documentation.

If you qualified under the Initial Qualifications, you must submit documentation of the following:

- ” Master’s degree or higher in a physical science - (copy of degree)
- ” 20 semester hours in physics - (copy of college transcript or letter from college stating hours)
  Note: If the degree is in physics, this documentation will not need to be submitted.
- ” 20 contact hours of specialized training in surveying mammography equipment
- ” experience conducting surveys - one mammography facility & 10 mammography units

If you qualified under the Alternative Initial Qualifications, prior to April 28, 1999, you must submit the following documentation:

- ” Bachelor’s degree or higher in a physical science - (copy of degree)
  Note: training and experience must be met after fulfilling degree requirements.
- ” 10 semester hours in physics - (copy of college transcript or letter from college stating hours)
  Note: If the degree is in physics, this documentation will not need to be submitted.
- ” 40 contact hours of specialized training in surveying mammography equipment
- ” experience conducting surveys - one mammography facility & 20 mammography units

3. Continuing experience and education:

- ” 15 CEUs in over a 36 month period (copies of certificates)

As of April 28, 1999 you must document the performance of surveys of a total of two mammography facilities and six mammography units over 24 months. Documentation of surveys will be required; **self-attestations are not accepted**. *(Inspectors will start reviewing records 04-28-2001.)*

TDH
TEXAS DEPARTMENT OF HEALTH

FEES FOR ACCREDITATION AND/OR CERTIFICATION OF MAMMOGRAPHY FACILITY

Each new application for accreditation and/or certification of a mammography facility shall be accompanied by the appropriate fees. In addition, each renewal accreditation application shall be accompanied by the appropriate fees. No application will be accepted for filing or processed prior to payment of the full amount due. [25 TAC §289.230 (ee) and §289.204 (h)]

- The fee(s) for accreditation of your mammography facility will be one or more of the following:

  - Accreditation for the first mammography unit $ 720.00

  - Accreditation fee for each additional mammography unit
    (Number of additional mammography unit(s) x $345.00) _____

ACCREDITATION TOTAL DUE **$** _____

- The fee for certification of your mammography facility will be:

  - $422.00 per mammography unit
    (number of mammography unit(s) x $422.00) $ _____

CERTIFICATION TOTAL DUE **$** _____

TOTAL DUE WITH APPLICATION(S) $ _____

Please complete this form and submit it with your application so that your request can be processed in a timely manner. If you have any questions regarding the payment of these fees, you may contact the accounting office of the Bureau of Radiation Control at (512) 834-6688.

Name of facility: _____